



T.O.S.C.A. Workstation

with TMS-3 AutoTopographer



USER'S MANUAL

Document No. 310599001

Version 1.0

Closing date 01/2000

TMS-3 Software V 2.2

T.O.S.C.A Software V 2.2

OPASS Software V 2.2

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Dear customer,

you have decided to use the T.O.S.C.A. TMS-3 Workstation.
We congratulate you on your decision!

You now own an advanced system for the topographic acquisition, evaluation and subsequent correction of the cornea of the human eye.

This system enables you to generate data records for ablation specific to each individual patient with high precision and transfer the data to the Excimer laser MEL 70 G *Scan* for carrying out the treatment.

The video monitor supplying a permanent image of the TMS-3 AutoTopographer camera picture and the TFT flat screen monitor displaying the user surface in large size will facilitate your work.

If you have any questions or would like to make any comments, please contact the following address:

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1 General information

1.1 Machine identification data

Machine data

Model designation: T.O.S.C.A. TMS-3 Workstation

Serial number: _____

Order number: _____

Year of construction: _____

TMS-3 software

License ID: _____

Serial number: _____

T.O.S.C.A. software

License ID: _____

Serial number: _____

WIN 98 operation system

Serial number: _____

Distributor

Firm/name: _____

Address: _____

Phone no.: _____

1.2 Document data

Document type: User's manual

Document number: 310599001

Version: 1.0

Closing date: 01/2000

1.3 Purpose of this document

This User's Manual makes the user of the T.O.S.C.A. TMS-3 Workstation familiar with the construction, operation, setting-up, handling, safety instructions, cleaning and maintenance of the system.

1.4 Availability of the User's Manual

Always keep the User's Manual and the other documents available to the operator.
The User's Manual should always be readily available for consultation.

1.5 Complete documentation

The scope of delivery of T.O.S.C.A. TMS-3 Workstation the system also comprises the product descriptions of the system components.

**Caution!**

The correct use of the TMS-3 AutoTopographer and the handling of the TMS-3 software are described in the Operator Manual of the supplier, Fortune Technologies, which is supplied with the machine.

The correct use of the computer and the computer peripherals is described in the documentation of the respective suppliers. The documentation is supplied with the machine.

The correct use of the 9" video monitor is described in the video monitor supplier's documentation.

The correct use of the 15" TFT flat screen is described in the screen supplier's documentation.

1.6 Operators

**Danger!**

The system must only be used by trained ophthalmologists instructed by Asclepion-Meditec in the construction, operation, handling, safety instructions, cleaning and maintenance of the machine.

The instruction shall be recorded and signed in a transfer certificate.

Additional requirements, qualifications or know-how are identified in the chapters of this User's Manual.

**Danger!**

The TOSCA program should not be solely relied on for determining pre-operative or post-operative procedures. As there is potential for serious injury including patient discomfort, pain, disorientation, loss of degrees of sight and blindness from improper use, at all times the user of the software should be a trained ophthalmologist familiar with the use and operation of the software and theories behind TOSCA.

The user of the program should rely on his or her own skill, knowledge, expertise and judgment when making decisions as to operative procedures and should not rely solely on the suggested parameters provided by the software, which is a calculating tool only dependent on data acquired by topography machines.

2 Machine description

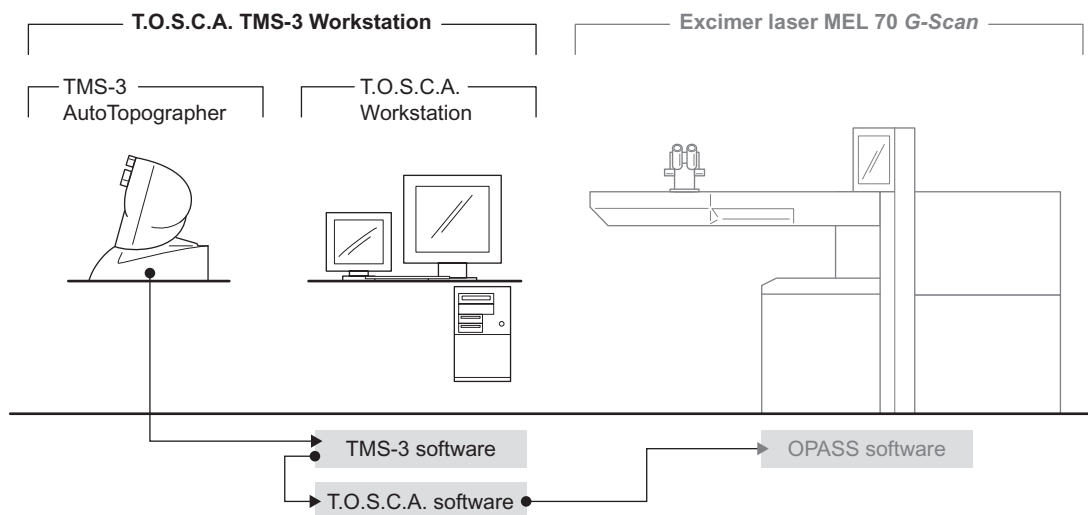
2.1 Concept

The T.O.S.C.A. TMS-3 Workstation is an advanced system for the acquisition and diagnosis of the superficial conditions of the cornea. The system supplies data for the planning, design and later performance of refractive intervention with the Excimer laser MEL 70 G Scan.

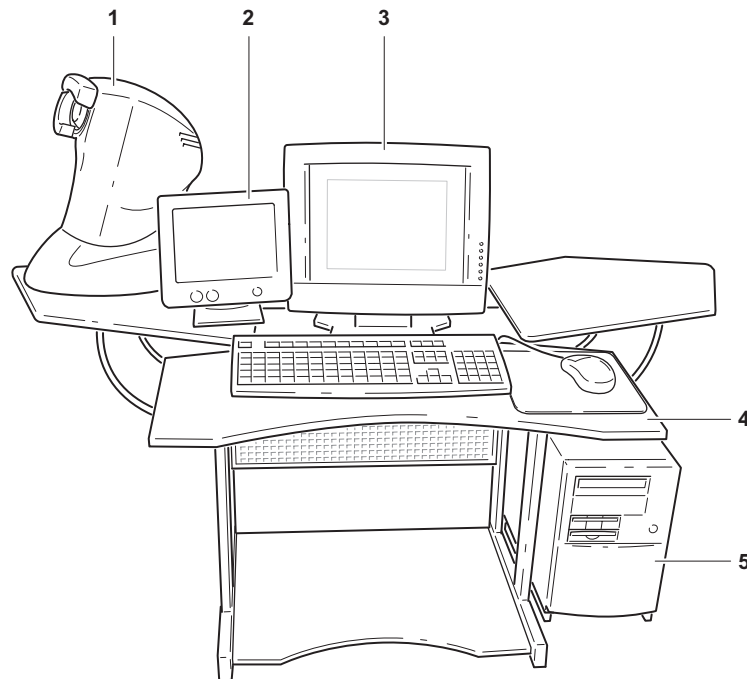
With a CCD camera, the TMS-3 AutoTopographer scans the patient's eye and generates the elevation contour of the cornea. The required data record is generated by the TMS-3 software supplied with the TMS-3 AutoTopographer.

The TMS-3 data record is sent to the T.O.S.C.A. software. The user can verify the data string with the T.O.S.C.A. software, reference it to other diagnostic data, edit data and finally generate a data record for an Excimer laser MEL 70 G Scan.

Now the OPASS software processes the data on the Excimer laser MEL 70 G Scan.



2.2 Construction

**Legend:**

- 1 TMS-3 AutoTopographer with power supply cable and parallel cable to the computer
- 2 Video monitor 9" with power supply cable and connecting cable to the TMS-3 AutoTopographer
- 3 TFT flat screen 15" with power supply unit and connecting cable to the computer
- 4 Computer table
- 5 Computer with power supply cable, mouse and keyboard

2.3 Function

The CCD camera of the TMS-3 AutoTopographer produces the elevation contour of the examined patient's eye.

The image captured by the camera is displayed on the video monitor in real-time mode.

The connected computer processes all data and allows user intervention with the software.

The TMS-3 software interprets the results of the camera and generates the data records.

These data records are sent to the T.O.S.C.A. software for processing. The user can verify the data contents, reference data to other diagnostic data and edit data.

The revised data records can then be transferred to an Excimer laser MEL 70 G *Scan* for further processing by the OPASS software.

2.4 Technical data

T.O.S.C.A. TMS-3 Workstation (overall system)

Dimensions W x D x H:	1.5 m x 1.0 m x 1.4 m
Weight:	40 kg
Power supply:	220–230 V, single-phase, 6 A, 50–60 Hz
Power consumption:	150 W
Class of electric protection:	1, type B, continuous service
License/test:	CE label
Ambient conditions:	15–35°C, 20–50 % RH

TMS-3 AutoTopographer



Caution!

For technical data and further specification details, please refer to the operator manual of the supplier, Fortune Technologies.

Computer



Caution!

For technical data and further specification details of the computer, please refer to the computer supplier's documentation in the supply.

Video monitor 9"



Caution!

For technical data and further specification details of the video monitor, please refer to the video monitor supplier's documentation in the supply.

TFT flat screen 15"**Caution!**

For technical data and further specification details of the TFT flat screen, please refer to the screen supplier's documentation in the supply.

Computer table

Dimensions W x D x H: 1.5 m x 1.0 m x 0.8 m

Weight: 26 kg

Material: Metal frame with plastic-coated table top panels

Carrying power: 12 kg each panel

3 Safety instructions

3.1 Customer's safety obligations

The T.O.S.C.A. TMS-3 Workstation was designed and produced in accordance with the applicable harmonized norms and further technical specifications. It is a state-of-the-art product and warrants the highest measure of safety.

This level of safety can be maintained in practical use of the system only if all required measures are taken. It is the obligation of the customer of the system to plan and supervise the performance of these measures.

The customer is responsible, in particular to ensure the following:

- to use the system only for the intended purpose;
- to operate the system only in perfect technical state with no function impaired;
- to maintain the User's Manual and all OEM documentation material in good condition and complete and store them on or near the machine;
- to allow only sufficiently qualified and authorized personnel to operate, maintain and repair the machine;
- to ensure regular instruction of such personnel in all matters pertaining to the machine and any of its components and make certain that all operators know the User's Manual and, in particular, the safety instructions;
- to make certain that none of the hazard warning labels on the system is removed or made illegible.

3.2 Safety alert symbols

The following safety alert symbols indicate important safety messages in this User's Manual. When you see this symbol, carefully read the message that follows be alert to the possibility of personal injury or death.



Danger!

This symbol indicates a hazardous situation which, if not avoided, will result in death or serious injury.



Caution!

This symbol indicates a hazardous situation which, if not avoided, will result in damage to the machine, material or the environment.



Note!

This symbol indicates information for the better understanding of the machine.

3.3 Concrete safety instructions

**Danger!**

The TOSCA program should not be solely relied on for determining pre-operative or post-operative procedures. As there is potential for serious injury including patient discomfort, pain, disorientation, loss of degrees of sight and blindness from improper use, at all times the user of the software should be a trained ophthalmologist familiar with the use and operation of the software and theories behind TOSCA.

The user of the program should rely on his or her own skill, knowledge, expertise and judgment when making decisions as to operative procedures and should not rely solely on the suggested parameters provided by the software, which is a calculating tool only dependent on data acquired by topography machines.

**Danger!**

All work on the electrical equipment of the system must only be carried out by a trained electrician.

It is not allowed to connect several components of the system by portable multiple socket outlets sharing a common grounding cable.

Always use the isolating transformer with multi-outlet distribution unit supplied with the machine.

Never clean or bring the electrical components of the system in contact with water or a similar liquid.

Lay the electrical cables and lines supplying the system in such a way that they do not constitute a tripping hazard.

Regularly inspect the safe standing of the system.

Do not make any changes to any system of the component without the supplier's authority.

Use only original replacement parts / original wearing parts / original accessory items. These parts and items are specially designed for the system. The use of parts other than original does not ensure design and manufacture in accordance with the service and safety requirements of the machine.

Parts and optional accessories which are not supplied with your order are not released by us for use with your particular system.

Inspect the electrical equipment regularly for proper seating and connection, damage to cables, lines and housing.

Disconnect the power supply immediately in case of fire.

Extinguish fire only with CO₂ or powder extinguisher.

4 Transport

4.1 Delivery

The consignment with the T.O.S.C.A. TMS-3 Workstation was delivered to our carrier in undamaged condition and complete with all required papers. The carrier delivering the system to your place is responsible for speedy and safe transport and delivery of the consignment to you without damage.

If on inspection of the consignment on receipt you find short delivery or damage in transit, this is the responsibility of the carrier delivering the consignment. If you find damage to the consignment in transit, please observe the following points:

- Insist that carrier make a note of the nature of the defect on the consignment note.
- The carrier should immediately inspect the damage or determine the value of the items in short delivery.
- Inform the competent insurance company of the damage or short delivery without delay. Only the insurance company will pay for the supply of the lost or damaged items in the consignment.
- If you fail to note any damage during a visual inspection of the consignment packages but on unpacking you find that a component of the system has been damaged and provided such damage has been caused in transit, inform the carrier of the facts without delay and insist that an inspection of the system components is made.
- Do not dispose of the original packaging unless all matters have been settled with the carrier and the insurance company.

4.2 Transfer to new site

If later you want to transfer the system to a new site, observe the following points:

- Make sure that no component can drop to the ground.
- The floor over which the system is transported should be level and have sufficient carrying power for vibration-free transport of the system.

**Caution!**

The system is a measuring instrument of high precision which must not be exposed to strong vibration.

Non-level ground can damage the system.

5 Setting-up

5.1 Requirements on the room

The room in which the T.O.S.C.A. TMS-3 Workstation is installed and operated should permit electrical supply in accordance to national requirements, have a firm floor with a minimum carrying capacity of 500 kg/m².



Danger!

Use the system only in a room with electrical installation satisfying the national requirements.

5.2 Unpacking

All supplied components will be unpacked by a service technician of Asclepion-Meditec.

5.3 Check for short delivery

Together with the Asclepion-Meditec service technician, inspect the consignment if all components needed to operate the system have actually been delivered.

The system consists of the following components:

- TMS-3 AutoTopographer with power supply cable, parallel cable to the computer and the operator manual of the supplier, Fortune Technologies;
- the computer with power supply cable, mouse, keyboard, and instruction material
- the 15" TFT flat monitor screen with power supply unit, connecting cable to the computer, and instruction material
- the 9" video monitor with power supply cable, connecting cable to the TMS-3 AutoTopographer, and instruction material
- the isolating transformer with multi-outlet distribution unit (5 outlets)
- the computer table
- one ZIP installation disk with the T.O.S.C.A. software
- one 3½" installation disk with the TMS-3 software
- the user's manual of the supplier, Asclepion-Meditec

5.4 Installation and layout of the system components

All system components are installed by a service technician of Asclepion-Meditec.

The layout of the system components is largely determined by the shape of the computer table. You can arrange the monitor screens to your most comfortable position.



Danger!

Cable ends and components live with electric power can cause electric injury.

Lay the electrical cables and lines supplying the system in such a way that they do not constitute a tripping hazard.



Caution!

Wrongly placed or improperly mounted parts can drop to the ground and cause personal injury.

Improperly installed cables and lines (e. g., if laid with close bending radius) can smoulder or catch fire.

Electronic assemblies can be damaged by electrostatic processes.

5.5 Initial instruction in the use of the system

The service technician from Asclepion-Meditec installing the system carries out the function test and instructs the operators of the system in its use as required under MPG and EC directive.

The fact that the instruction was carried out shall be recorded in the delivery document of the system.

6 Start-up

6.1 Qualification of the start-up operator

The first start-up of a new system is the job of an authorized representative of Asclepion-Meditec who explains all involved steps to the customer's operators.

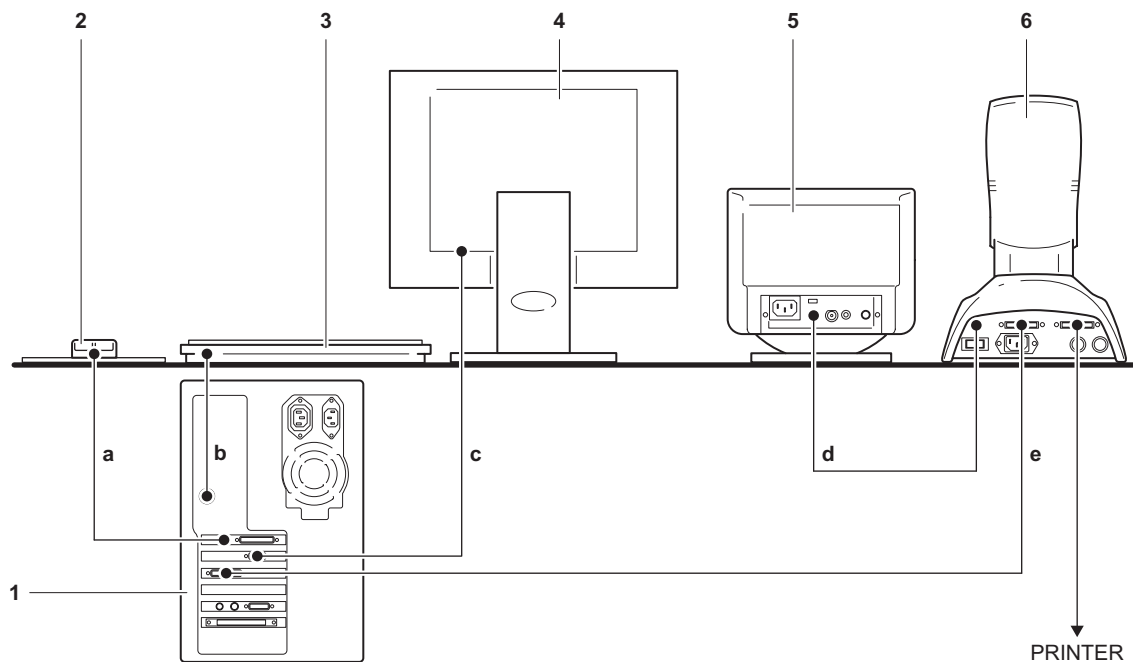
6.2 Connection of all system components

All connections are made on the rear of each component.



Caution!

Make sure of the proper seating of all plugs.



System components:

- 1 Computer
- 2 Mouse
- 3 Keyboard
- 4 15" TFT flat screen
- 5 9" video monitor screen
- 6 TMS-3 AutoTopographer

Connections:

- a Mouse cable
- b Keyboard cable
- c Monitor screen connection
- d TMS-3 - monitor screen
- e TMS-3 - computer

6.3 Mains power supply

The T.O.S.C.A. TMS-3 Workstation is supplied with single-phase power 220–230 V, 50 Hz, 6 A fused.

To connect the system to the power source, proceed as follows:

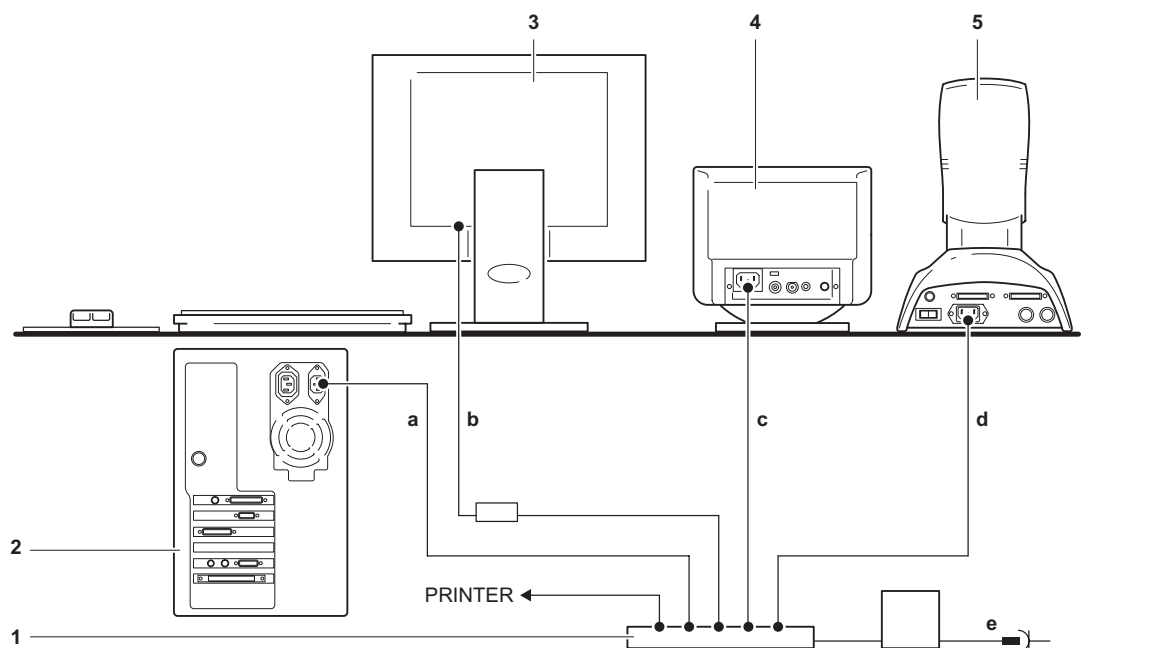
1. Make sure that all system components and the isolating transformer are turned off.
2. Make sure that the voltage specified on the nameplate on the rear of each system component agrees with the voltage of your socket outlet.
Check to make sure that the power supply cable can be used on your power source.
3. Connect all system components to the multi-outlet distribution unit using the delivered power supply cables.
4. Plug the isolating transformer in a properly grounded socket outlet.



Danger!

Use the system only in a room with electrical installation satisfying the national requirements.

It is not allowed to use portable multiple socket outlets sharing a common grounding cable to connect several components of the system.



System components:

- | | |
|---|---|
| 1 | Isolating transformer with multi-outlet distribution unit (5 outlets) |
| 2 | Computer |
| 3 | 15" TFT flat screen |
| 4 | 9" video monitor screen |
| 5 | TMS-3 AutoTopographer |

Connections:

- | | |
|---|--|
| a | Computer power supply cable |
| b | Power supply cable with power supply unit of the 15" TFT flat screen |
| c | 9" video monitor screen power supply cable |
| d | TMS-3 AutoTopographer power supply cable |
| e | Isolating transformer mains power connection |

6.4 Turning the system on/off

Turn the T.O.S.C.A. TMS-3 Workstation on/off at the isolating transformer.

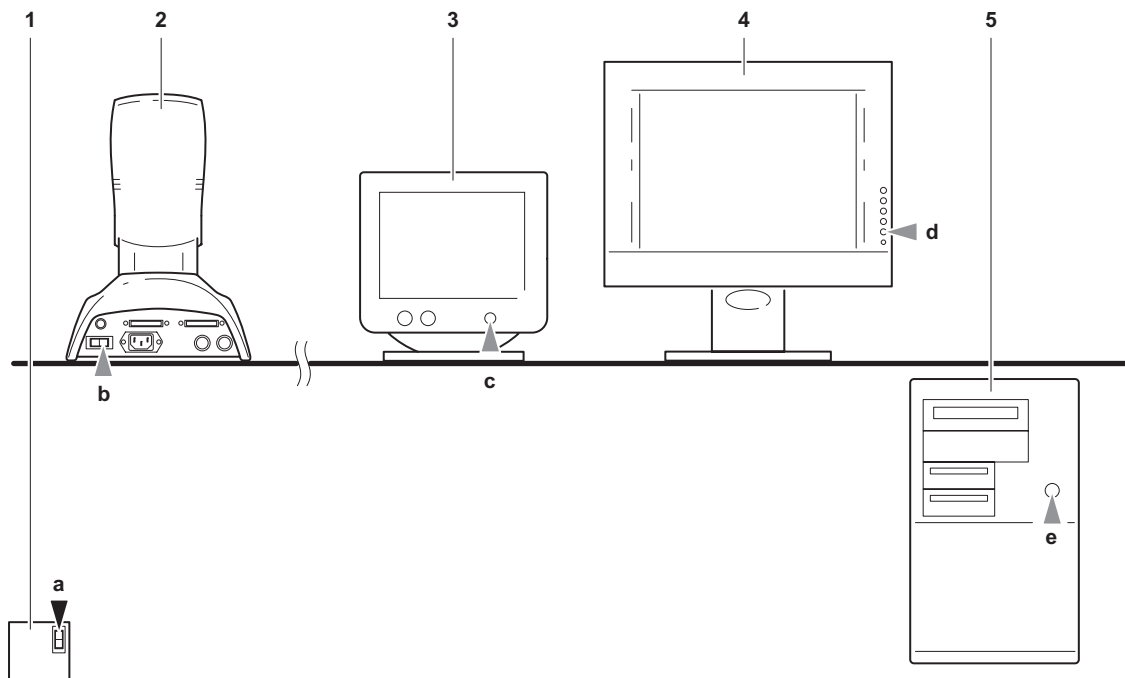
It is also possible to turn the system components on or off at the mains switch of each component.

For details of the location of the mains power switch on each component, please refer to the illustration below.



Note!

Please turn the system on or off at the isolating transformer.



System components:

- 1 Isolating transformer
- 2 TMS-3 AutoTopographer
- 3 9" video monitor screen
- 4 15" TFT flat screen
- 5 Computer

On/off switch

- a Isolating transformer on/off switch
- b TMS-3 AutoTopographer on/off switch
- c Video monitor screen on/off push-button
- d TFT flat screen on/off push-button
- e Computer on/off push-button

6.5 Installation of the software

The complete software required by the system is already installed on the computer and ready for use when it is delivered.

If you want to re-install the software, follow the instructions on this and the following pages.



Caution!

Store the installation disks at a safe place. Do not expose the installation disks to strong magnetic field, heat or cold, direct sunlight, moisture or dust.

6.5.1 Installation of the TMS-3 software

For a description of the installation of the TMS-3 software, refer to the delivered operator manual of the supplier, Fortune Technologies.

6.5.2 Installation of the T.O.S.C.A. software

1. Start Windows, unless already running.
2. Load the T.O.S.C.A. installation disk in the ZIP drive of the computer.
3. Wait for the installation window display.

The installation disk is self-starting.
If the installation will start automatically, start it manually by selecting the SETUP.EXE file.



Please read the disclaimer notice carefully.

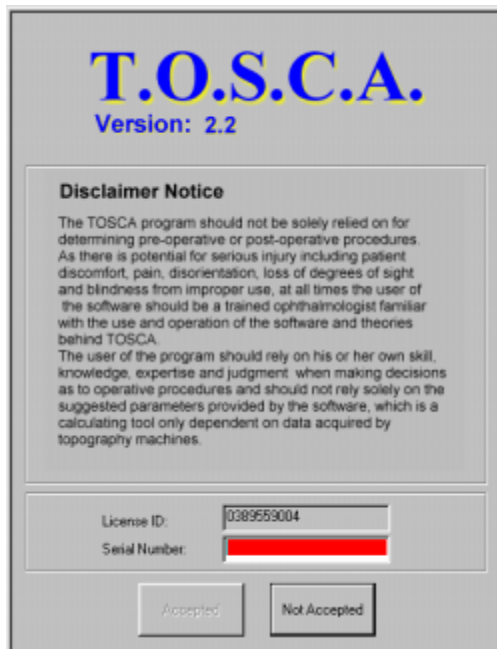
If you do not agree to the terms and conditions, click <Not Accepted>.

If you agree to the terms and conditions, you can proceed with the installation.

Record your license ID.

To know your serial number, please dial the following number: +49 36 41/ 65 22 78.

You can also send us an e-mail or a fax transmittal.



T.O.S.C.A.
Version: 2.2

Disclaimer Notice

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License ID: 0389559004
Serial Number: [Redacted]

Accepted Not Accepted

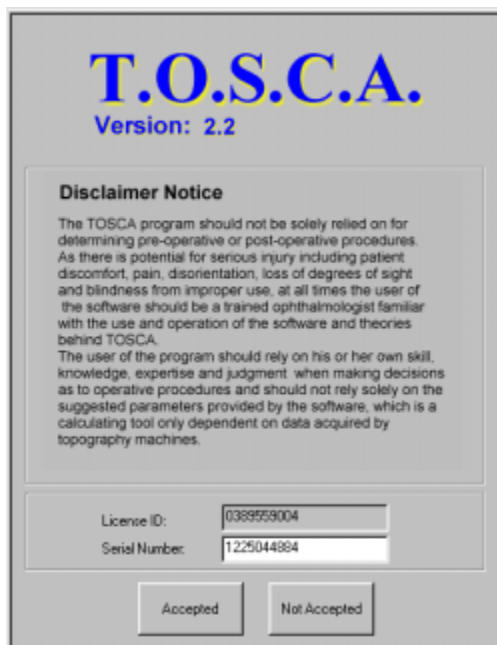
4. Enter your serial number in the red input field. If the number is correct, the color of the input field changes to white.

If you want to proceed with the installation click the <Accepted> button once

If you do not want to go ahead with the installation, click the <Not Accepted> button once.

This completes the installation process.

Please remove the installation disk from the ZIP drive of your computer.



T.O.S.C.A.
Version: 2.2

Disclaimer Notice

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License ID: 0389559004
Serial Number: 1225044884

Accepted Not Accepted

7 Operation

7.1 Qualification of the operator

The T.O.S.C.A. TMS-3 Workstation must only be used by qualified and instructed ophthalmologists.



Danger!

The TOSCA program should not be solely relied on for determining pre-operative or post-operative procedures. As there is potential for serious injury including patient discomfort, pain, disorientation, loss of degrees of sight and blindness from improper use, at all times the user of the software should be a trained ophthalmologist familiar with the use and operation of the software and theories behind TOSCA.

The user of the program should rely on his or her own skill, knowledge, expertise and judgment when making decisions as to operative procedures and should not rely solely on the suggested parameters provided by the software, which is a calculating tool only dependent on data acquired by topography machines.

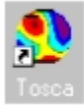
The operator of the system must have knowledge of the WIN 98 operating system.

7.2 The TMS-3 software

The use of the TMS-3 software is described in the delivered operator manual of the supplier, Fortune Technologies.

7.3 The T.O.S.C.A. software

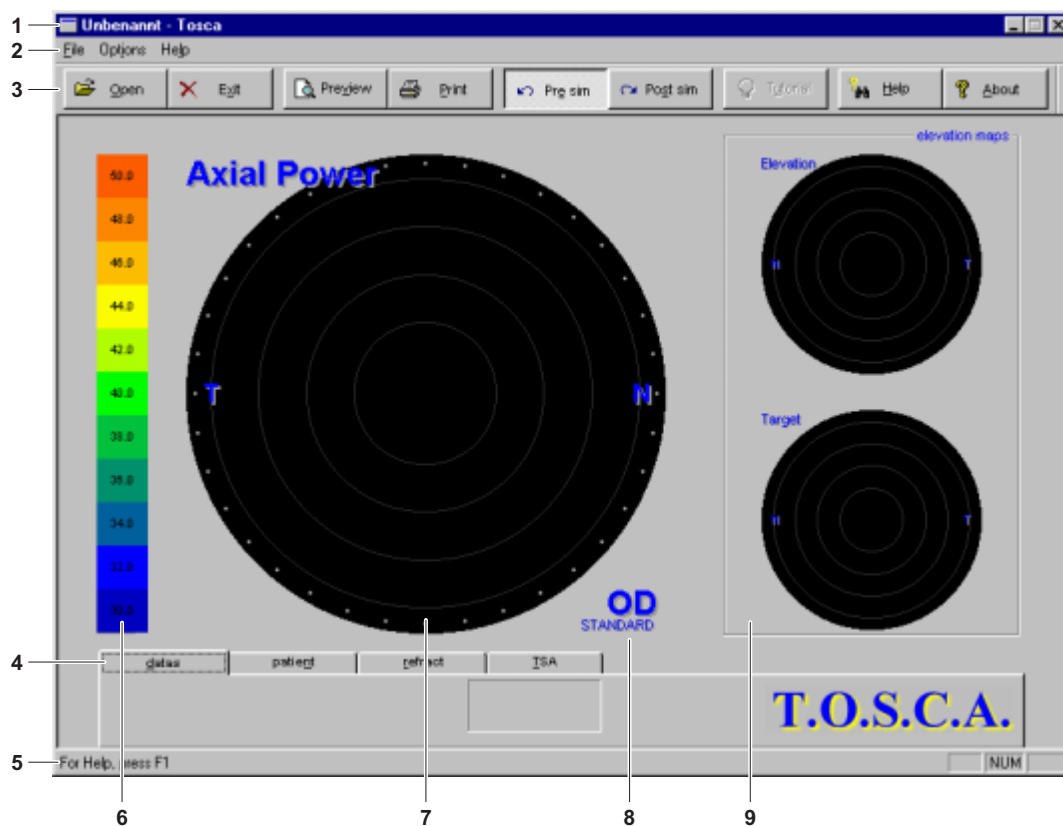
7.3.1 Starting the T.O.S.C.A. software



To start the software, double-click the TOSCA icon.

The main menu of the software is displayed.

7.3.2 The main menu



Legend:

- 1 Top status line
- 2 Menu bar
- 3 Icon bar
- 4 Register cards
- 5 Bottom status line
- 6 Color scale
- 7 Power map
- 8 Eye type and machine type
- 9 Elevation maps

7.3.3 The top status line



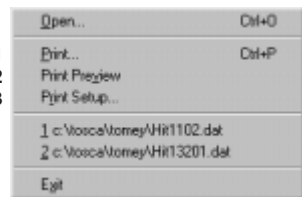
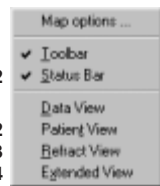
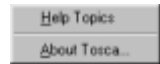
Legend:

- 1 File name of the current file
- 2 Software name
- 3 Minimize window
- 4 Maximize window
- 5 Close the software

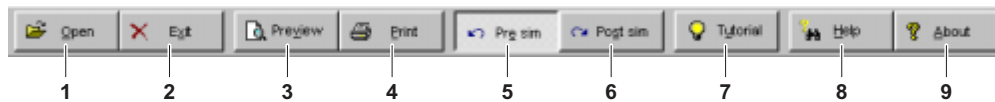
7.3.4 The menu bar



Legend:

- | | | |
|---|---|--|
| 1.1
1.2.1
1.2.2
1.2.3
1.3
1.4 |  | 1.1 Opens the window to select a patient data record
1.2.1 Prints the current file
1.2.2 Opens the file print preview window
1.2.3 Opens the "Printer Set-up" window of the currently selected printer
1.3 Displays the two files opened last
1.4 Quits the current program |
| 2.1
2.2.1
2.2.2
2.3.1
2.3.2
2.3.3
2.3.4 |  | 2.1 Opens the "Map Options" selection window
2.2.1 Hides/shows the icon bar
2.2.2 Hides/shows the bottom status bar
2.3.1 Displays the content of the "Data" register card
2.3.2 Displays the content of the "Patient" register card
2.3.3 Displays the content of the "Refract" register card
2.3.4 Displays the content of the "TSA" register card |
| 3.1
3.2 |  | 3.1 Displays help topics for using the T.O.S.C.A. software
3.2 Displays information on the T.O.S.C.A. installation data |

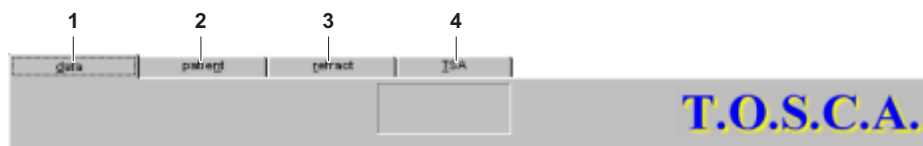
7.3.5 The icon bar



Legend:

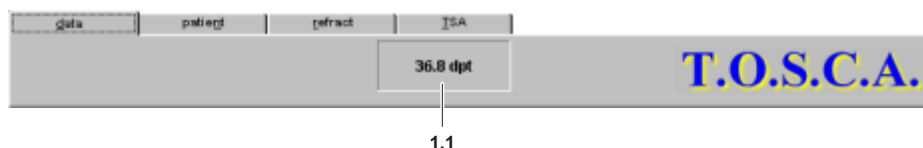
- 1 Opens the window to select a patient data record
- 2 Quits the current program
- 3 Opens the print preview window of the file
- 4 Prints the current file
- 5 Displays the current file prior to simulation of treatment
- 6 Displays the current file after simulation of treatment
- 7 Opens the tutorial on T.O.S.C.A.
- 8 Displays help topics for using the T.O.S.C.A. software
- 9 Displays information on the T.O.S.C.A. installation data

7.3.6 The register cards



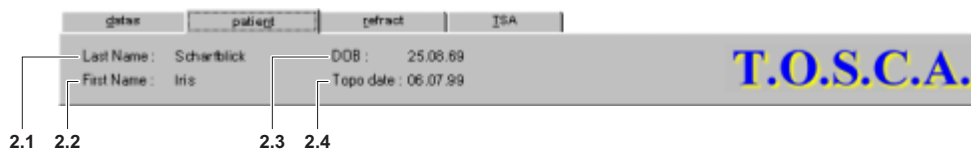
Legend:

- 1 Displays the value under the mouse pointer
- 2 Displays the available patient data
- 3 Enables entry of the refraction data
- 4 Enables entry of the shift of the reference area in the Z axis

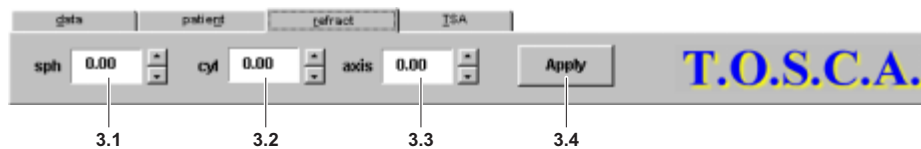


Legend:

- 1.1 Displays the value under the mouse pointer.


Legend:

- 2.1 Displays the patient's family name
- 2.2 Displays the patient's first name
- 2.3 Displays the patient's date of birth
- 2.4 Displays the date of the topographic image exposure


Legend:

- 3.1 Enables the entry of the correction values for the sphere data
- 3.2 Enables the entry of the correction values for the cylinder data
- 3.3 Enables the entry of the correction values for the axis data
- 3.4 Starts the new calculation with the refraction data

The newly calculated elevation contour is displayed in the "Target" window.

**Note!**

The values for sphere, cylinder and axis are entered with the arrow keys beside the input fields.

The values are entered in steps of 0.25 dpt and 5 °, respectively either as incrementing or decrementing value steps.

The maximum values for sphere and cylinder are $\pm 12,5$ dpt.

The maximum value for axis is 0–180 °.

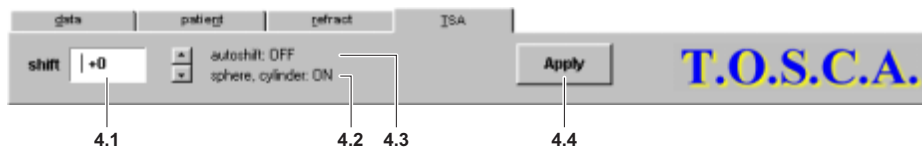
**Legend:**

- 3.5 Generates a data record for ablation on the Excimer laser MEL 70 G *Scan*.

The generated data record is written directly on a ZIP disk.

**Caution!**

Load a ZIP disk with sufficient free memory space in the ZIP drive of the computer before starting the <Shaping> function.

**Legend:**

- 4.1 Enables entry of the correction values for the shift of the reference area in the Z axis
- 4.2 Status message
- 4.3 Status message
- 4.4 Starts the new calculation with the refraction data.

The newly calculated elevation contour is displayed in the "Target" window.

**Note!**

The values for Z shifting are entered with the arrow keys beside the input fields.

The values are entered in steps of 1 μm either as incrementing or decrementing value steps.

The maximum value for Z shifting is $\pm 100 \mu\text{m}$.

The refraction data are still enabled in TSA mode even if the value calculated by the software is disabled in TASA mode.

After completing the <Apply> function, a new shift value can be defined by mouse-clicking the "Target" window.



Legend:

- 4.5 Generates a data record for ablation on the Excimer laser MEL 70 G Scan.

The generated data record is written directly on a ZIP disk.



Caution!

Load a ZIP disk with sufficient free memory space in the ZIP drive of the computer before starting the <Shaping> function.

7.3.7 The bottom status line



Legend:

- 1 Displays messages according to the current conditions.
- 2 Not assigned.
- 3 Indicates if the number field of the keyboard is turned on or off.
- 4 Not assigned.

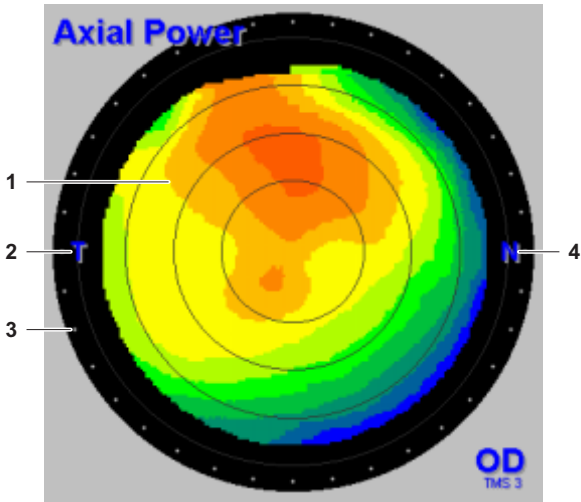
7.3.8 The color scale



The color scale displays all colors used, together with their dpt values.

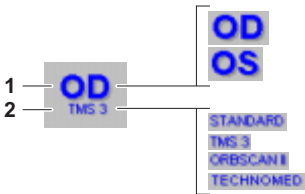
The color scale can change its appearance depending on the source of the invoked patient data record.

7.3.9 The power map



- Legend:
- 1 Displays the curvature of the cornea as a color contour, together with the assigned dpt values.
 - 2 Temporal
 - 3 Angle matrix in 10 ° steps
 - 4 Nasal

7.3.10 Eye type and machine type

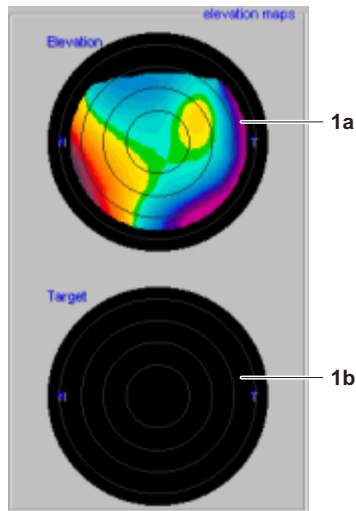


- Legend:
- 1 Displays the eye type
 - 2 Displays the machine type

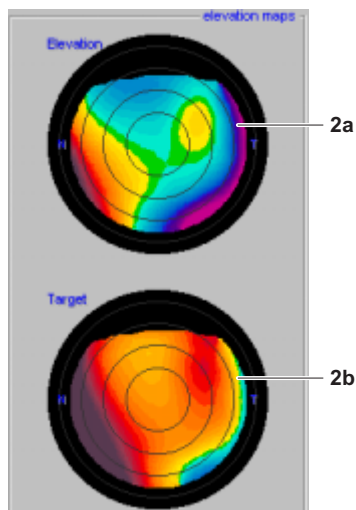
7.3.11 The elevation maps

Legend:

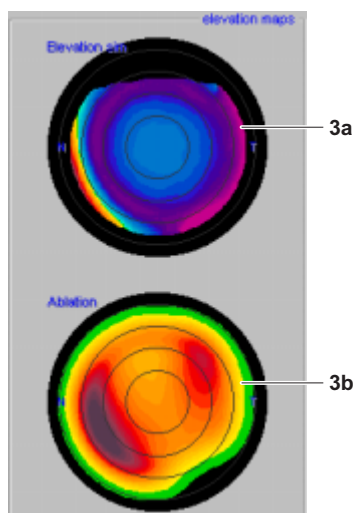
- 1a The "Elevation" window displays the elevation contour of the cornea.
Elevation is indicated in units of μm .
- 1b Before the <Apply> function is performed to obtain an elevation contour of the cornea, the "Target" window is blank.



- 2a After performing the <Apply> function the current display of the cornea in the "Elevation" window remains displayed.
- 2b After performing the <Apply> function the elevation contour of the "Elevation" window corrected for the entered refraction data is displayed in the "Target" window.
The elevation values are displayed in units of μm .



- 3a After using the <Shaping> function, the result of treating the cornea is displayed in a simulation capture in the "Elevation Sim" window.
- 3b After using the <Shaping> function, the "Target" window changes to the "Ablation" window.
The "Ablation" window displays the elevation values of the ablation to be made.
The elevation values are displayed in units of μm .



7.4 Making an examination

7.4.1 Instructing the patient

Explain the patient what is going to happen during the examination
Explain the further procedural steps to the patient.



Caution!

The set-up of the patient place and the handling of the TMS-3 AutoTopographer are described in the operator manual of the supplier, Fortune Technologies.

7.4.2 Making a topographic image exposure

The topographic image exposure is made and the appropriate patient data record generated with the TMS-3 AutoTopographer using the TMS-3 software.



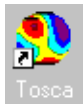
Caution!

The topographic image exposure is described in the operator manual of the supplier, Fortune Technologies.

7.4.3 Generating a data record for ablation

The further processing of the topographic data runs under the T.O.S.C.A. software

1. Start the T.O.S.C.A. software.



To start the software, double-click the TOSCA icon.

The main menu of the software is displayed.

2. Invoke the patient database



Click <Open> in the icon bar of the main menu.

The patient database is displayed.

3. Select a patient data record

Open Topofile					
Last Name	First Name	Eye Type	Topo Device	Topo Date	Topo Time
BOZIKOVIC	SERGE	OD	TMS 3	10.08.99	17:11:18
BRIONES ALAMO	ANGELES	OD	TMS 3	22.06.99	17:30:21
CARRERA JEMINEZ	ANGELES	OD	TMS 3	22.06.99	11:16:29
DEGEEST	JORGE	OS	ORBSCAN II	5.07.99	08:54:30
SCHARFBLOCK	IRIS	OD	TMS 3	13.09.99	13:22:13
ENGELHARDT	MARGOT	OD	TMS 3	13.09.99	13:20:10
FEUCHTER	WILMA	OD	ORBSCAN II	5.29.98	07:30:05
FEUCHTER	WILMA	OD	ORBSCAN II	5.29.98	07:30:05
GEBAUER	REINHARD	OS	TMS 3	30.07.99	08:59:07
GERHARDT	RAINER	OD	TECHNOMED	07.01.1999	13:32:39
GERHARDT	RAINER	OD	TECHNOMED	07.01.1999	13:29:56
GERHARDT	RAINER	OD	TECHNOMED	07.01.1999	13:27:57

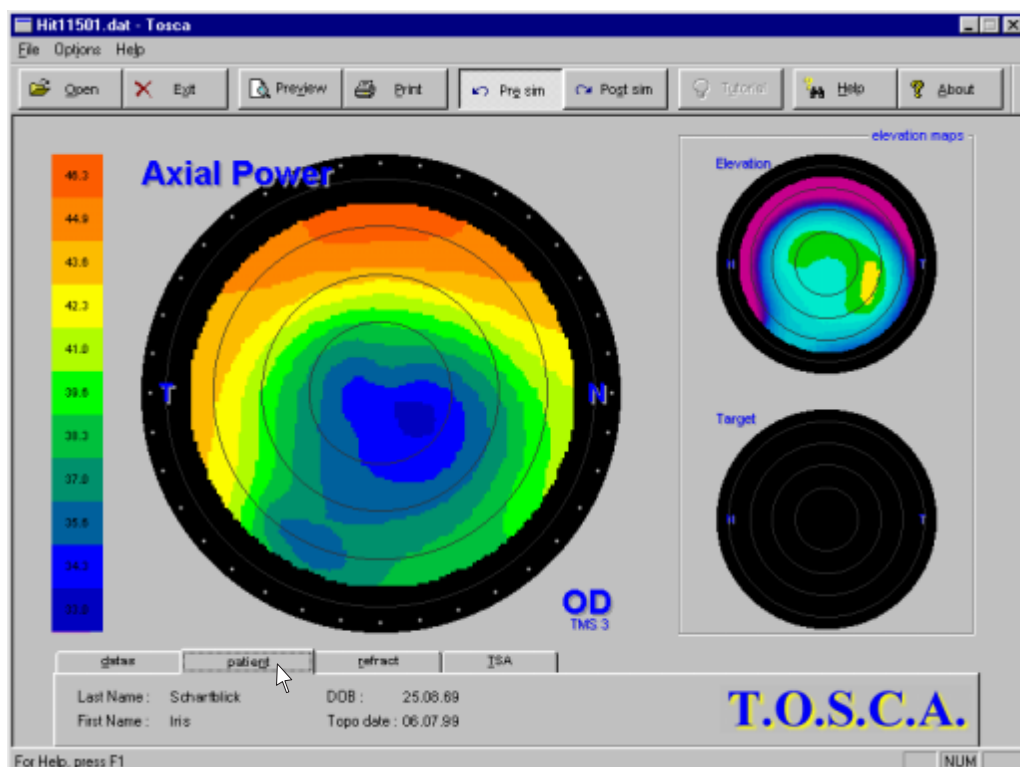
Click the required data record.

The selected data record is highlighted blue.

Confirm your selection by clicking <Open>.

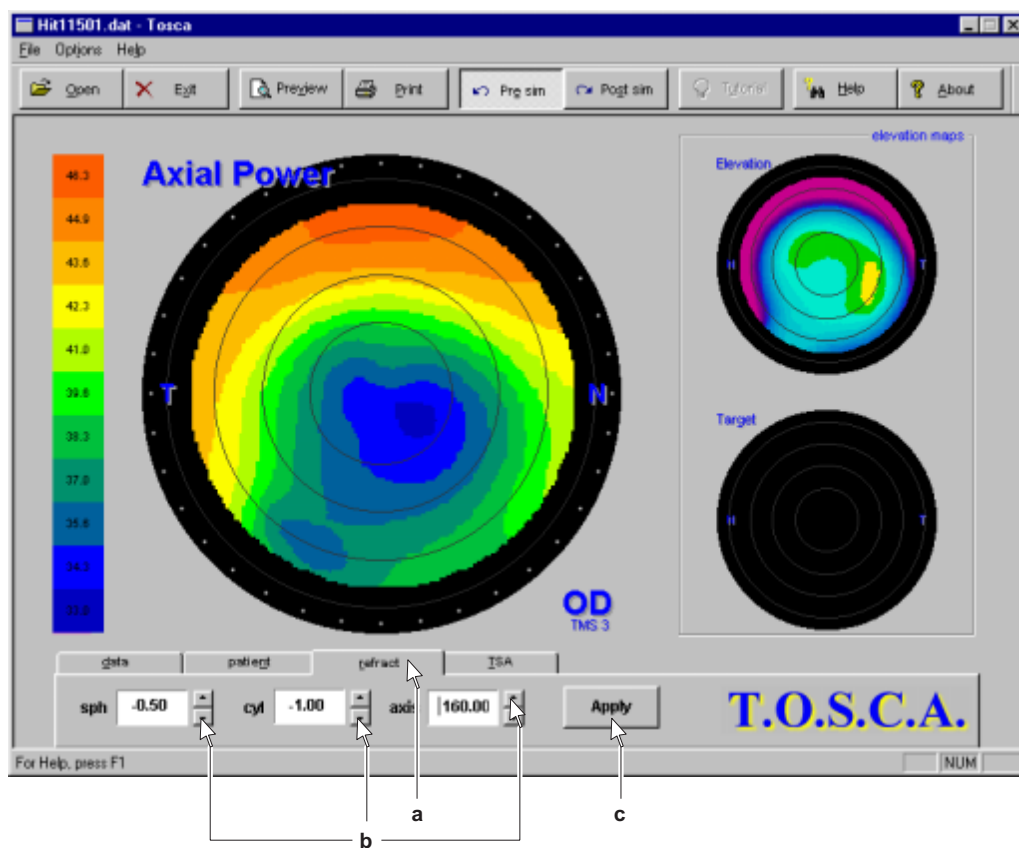
Click <Cancel> to exit the selection window without enabling a data record.

4. Verify the patient data



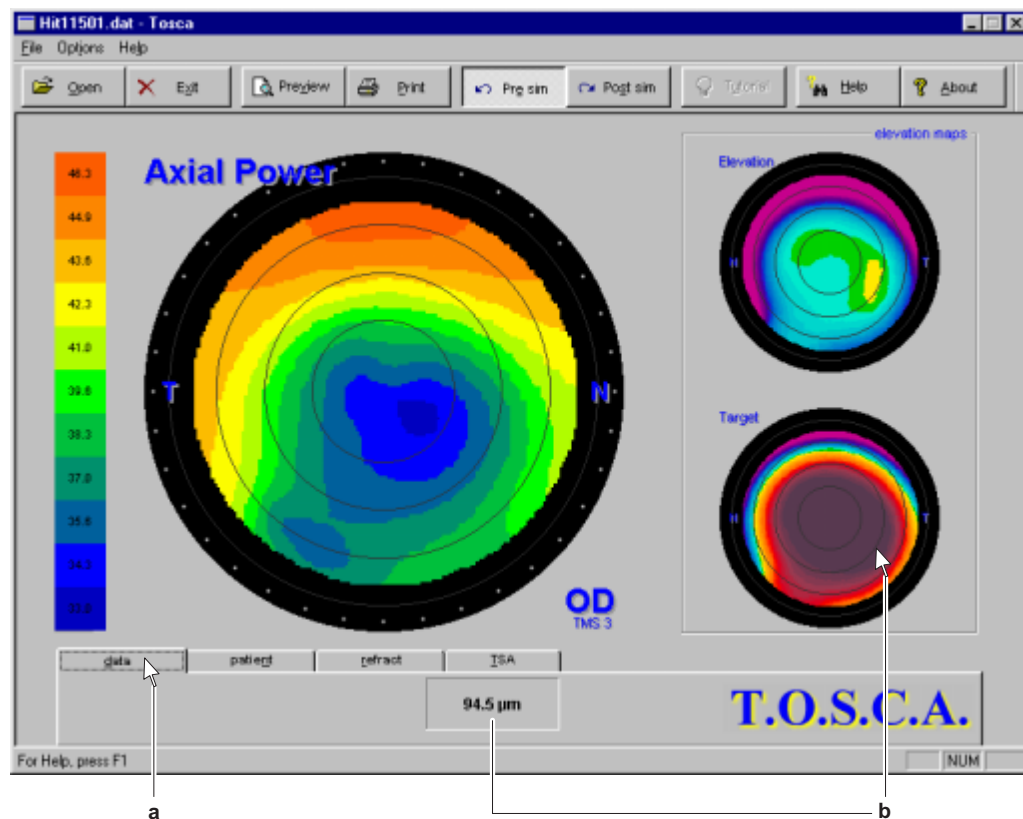
To verify the patient data, click the <Patient> register card.

5. Enter the refraction values



- a) Open the <Refract> register card.
- b) Enter the patient's current refraction values in the input fields.
- c) Click the <Apply> button to obtain the display of the new calculation in the "Target" window.

6. Determine the elevation values in the “Target” window

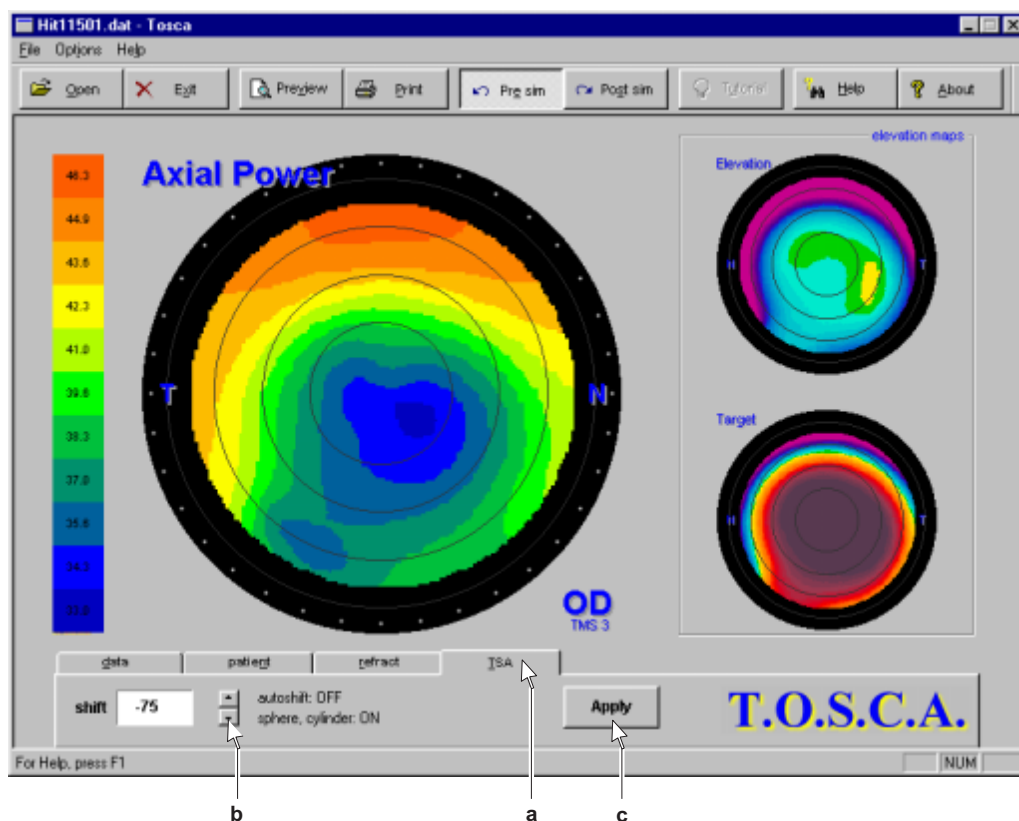


- a) Open the <Data> register card.
- b) Place the mouse pointer over the “Target” window.

The current value is displayed in the display window below the mouse pointer.

Determine the highest elevation value along the second ring (counting from the center point).

7. Set the depth of treatment



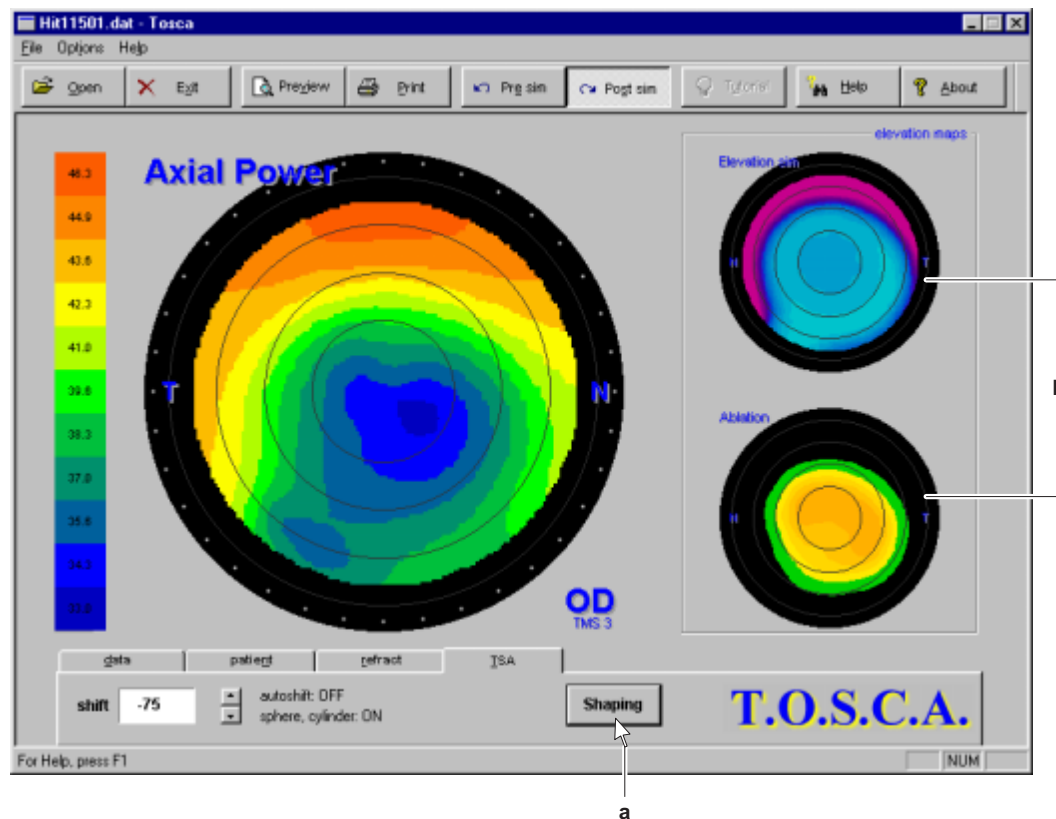
- Open the <TSA> register card.
- Enter the value of the shift of the reference area in the Z axis.
- Click the <Apply> button to obtain the display of the new calculation in the "Target" window.



Danger!

If you change the depth by a shift of the reference area in the Z axis, you also change the size of the treatment area.

8. Generate a data record for ablation



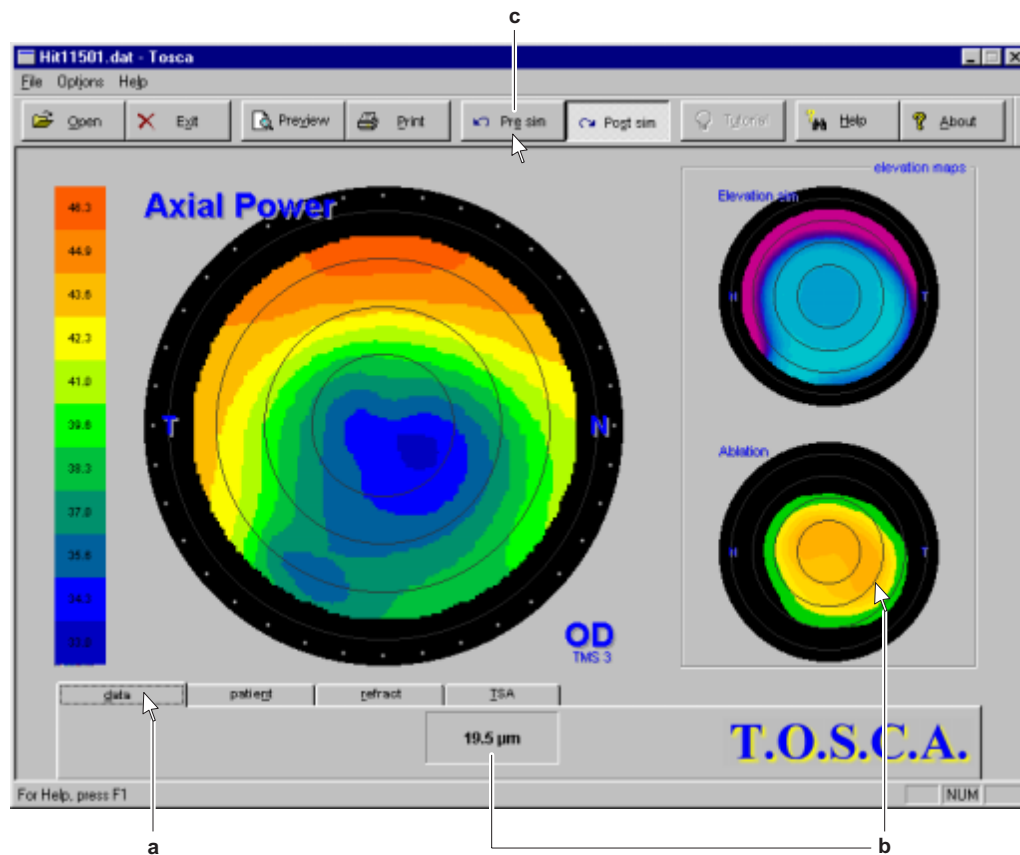
- a) Click the <Shaping> button.
A data record for ablation is generated.
The generated data record is written directly on the ZIP disk in the ZIP drive of your computer.
- b) After using the <Shaping> function, the result of treating the cornea is displayed in a simulation capture in the "Elevation Sim" window.
The "Ablation" window displays the elevation values of the ablation to be made.



Caution!

Load a ZIP disk with sufficient free memory space in the ZIP drive of the computer before starting the <Shaping> function.

9. Verify the result



- a) Open the <Data> register card.
- b) Place the mouse pointer above the "Target" window. The current value is displayed in the display window below the mouse pointer.
Adjust the elevation value to the patient data.
- c) Click the <Pre Sim> button to restore the status before the data record for ablation was generated.



Note!

The lowest point in units of μm should approximately be equal to the refraction (sph + cyl) in units of dpt, multiplied by $13 \mu\text{m}/\text{dpt}$ (plausibility check). If you are in doubt, select a new Z shift value.

- c) Click the <Pre Sim> button to restore the status before the data record for ablation was generated.

10. Correct the settings, if necessary

If you think that the depth should be corrected, open the <TSA> register card once more. Make the required change by entering a different value.

To obtain a new preview, repeat the <Apply> and <Shaping> functions.

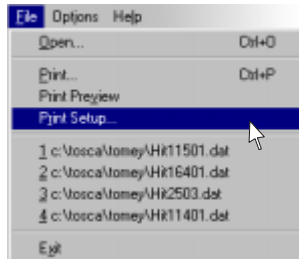


Danger!

If you change the depth by a shift of the reference area in the Z axis, you also change the size of the treatment area.

7.4.4 Printing out the data record overview

1. Print Set-up



Click the <Print Setup> button in the <File> menu.
 Select the printer that is connected to the system.
 Complete the required settings.
 To confirm the entries, click <OK>.



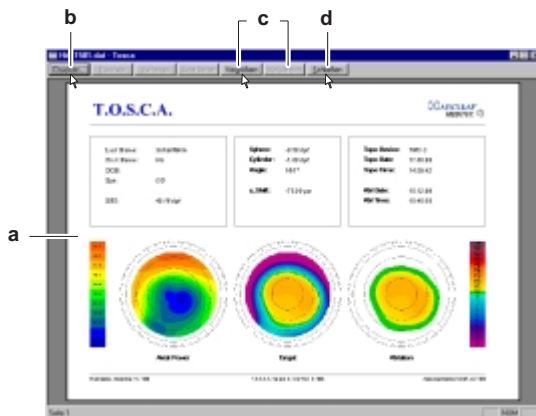
Note!

The data screen for the output of the data record overview uses a A4 landscape format as a default.

2. Print Preview



Click the <Preview> button on the icon bar.
 The "Print Preview" window is displayed.



- a) It contains an overview of all relevant data.
- b) A print-out can be obtained from the "Print Preview" window.
- c) The preview display can be zoomed in or out.
- d) Closes the "Print Preview" window.

3. Print



Click the <Print> button on the icon bar.
 The data record overview is printed out.



Note!

Print out the data on a color printer.

7.5 Transferring the data record to the Excimer laser MEL 70 G Scan

1. Remove the ZIP disk from the computer's ZIP drive.
2. Load the ZIP disk in the ZIP drive of the Excimer laser MEL 70 G Scan.
3. Start the OPASS software unless already started.
4. Select the required data record in drive "E:" and open the data record.

**Note!**

All patient data records use the extender "DAT".

5. Again verify the correctness of the selected patient data record.

**Danger!**

If by chance you should select wrong patient data, serious injury can be caused by the treatment.

6. Now you can start the treatment in accordance with the operating instructions and the application manual of the Excimer laser MEL 70 G Scan.

**Danger!**

This User's Manual of the T.O.S.C.A. TMS-3 Workstation is not an instruction to carry out the treatment on the Excimer laser MEL 70 G Scan. Always refer to the operating instructions and the application manual of the Excimer laser MEL 70 G Scan.

8. Troubleshooting

If you require the assistance of our customer service department or if you have a question relating to the machine and how it is handled, or the software, please call the Excimer hotline or contact the nearest distributor.

Excimer hotline:

Phone: +49 36 41/65 22 78

Facsimile: +49 36 41/65 39 31

e-mail: AMJ_EXCIMER_HOTLINE@compuserve.com

8.1 Problems with the hardware



Caution!

The T.O.S.C.A. TMS-3 Workstation contains no parts that can be maintained or repaired by the user.

Only our customer service technicians and other specialists trained by us are authorized to carry out service work on the system.

Any repair attempt by unauthorized personnel can lead to forfeiture of all warranty claims. Besides, functions of the system may be disrupted.

8.2 Fault messages when using the system

The computer of the T.O.S.C.A. TMS-3 Workstation displays fault messages in non-coded text format.


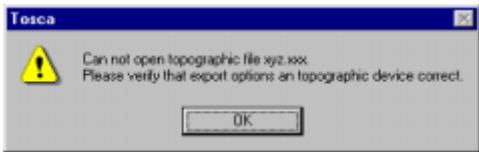

The message display should help you set the problem right.



Note!

This section only deals with fault messages of the T.O.S.C.A. software.

To set right software faults of other programs or of the operating system, refer to the appropriate system manual.

Fault message	Cause	Remedy
	The file you wanted was not found or is defective	Install the required file
	The installation of TOSCA was not successfully completed	Call the hotline
	The settings of the export options on the topographic unit were not correctly made	Correct the settings of the export parameters
		Call the hotline
	The connected ZIP drive is not enabled	Start the ZIP drive
	There is no ZIP disk in the drive	Load a ZIP disk
	The ZIP medium is full	Make sure that sufficient free storage space is available on the ZIP disk. Load a new ZIP disk if necessary.
	For other problems, go to the ZIP drive help function	Call the hotline

9. Cleaning and maintenance

9.1 Cleaning

Computer table, housings and monitor screens

Clean the computer table and the housings with a soft wet cloth. Remove obstinate dirt with a mild cleaner.

Clean the screens with a soft, dry cloth. Use special screen cleaner if necessary.



Danger!

Do not use a dripping wet cloth. There is risk of electric injury.



Caution!

Do not use aggressive or abrasive cleaner.

Optical components

All optical parts must be of very high quality. Protect all optical parts from damage and accumulation of dirt.



Caution!

Do not touch an optical surface.

Have customer service personnel clean the optical parts.

9.2 Maintenance

For details of maintenance intervals of the TMS-3 AutoTopographer, please refer to the operator manual of the supplier, Fortune Technologies.

There are no prescribed maintenance intervals for all other system components.



Caution!

Only Asclepion-Meditec technicians or specialists authorized by Asclepion-Meditec are permitted to carry out cleaning and maintenance of the system.

10. Further information

10.1 Accessories and replacement parts

Please note that under the Medical Equipment Act you are required to use parts tested and released for use with this system.

For information on certificates confirming the safe use of the system, please refer to the OEM documentation.

We urgently advise you not to use accessory components of other suppliers. Asclepion-Meditec cannot accept any liability for any such component.

10.2 Warranty

The T.O.S.C.A. TMS-3 Workstation is warranted for a period of 12 months after delivery ex works. The warranty covers all parts manufactured by us and all parts from other manufacturers installed in this system.

We reserve the right to repair defects in the system by replacement of the defective part. The replacement of any part is no reason to claim an extension of the warranty period.

The warranty prescribed by law is available for any part renewed by us.

Defects caused by improper handling of the machine are not covered by our warranty.

10.3 Customer service

If you require customer service or if you have any question regarding the T.O.S.C.A. TMS-3 Workstation, please call our Excimer laser hotline or your nearest distributor.

Phone: +49 36 41/65 22 78


Facsimile: +49 36 41/65 39 31

e-mail: AMJ_EXCIMER_HOTLINE@compuserve.com

Please note that supplier and distributor will only accept responsibility for the function, reliability and safety of the system if:

- the system was set up, started, maintained and repaired only by personnel authorized by it;
- the electrical installation conforms to the legal requirements;
- the system is used in accordance with the instructions.

10.4 Conformity statement



Asclepion-Meditec AG, Prüssingstraße 41, 07745 Jena, Germany

Kombination von Produkten mit CE-Kennzeichnung

Combination of CE-compliant products

- TMS 3
- Software Workstation
- TOSCA

Hiermit erklärt die Asclepion-Meditec AG nach Artikel 12 der EG-Richtlinie 93/42/EWG, daß die nachfolgend angeführten Gerätekombinationen bei bestimmungsgemäßen Einsatz der Einzelkomponenten möglich sind und die gegenseitige Vereinbarkeit gemäß den Vorschriften der Hersteller geprüft wurde. Die jeweiligen Gerätekombinationen wurden bei der Asclepion-Meditec AG geprüft und verpackt. Sachdienliche Benutzerhinweise, einschließlich der einschlägigen Hinweise der Hersteller, sind in der Gerätekombination beiliegenden Dokumentation enthalten. Die genannten Tätigkeiten wurden gemäß dem bei der Asclepion-Meditec AG eingerichteten Qualitätssicherungssystem durchgeführt und überwacht.

Herewith Asclepion-Meditec AG declares according to Article 12 of Medical Device Directive 93/42/EEC that the following combination of devices are legal if each single component is used in line with it's intended use and the combination is tested and packed by Asclepion-Meditec AG. Relevant information, including all operating manuals of the manufactures are included in the delivered documentation. All these actions were performed and controlled according to the Asclepion-Meditec AG Quality Management System.

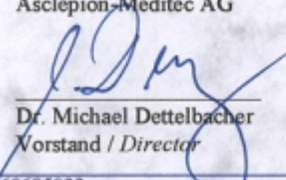
Folgende Gerätekombinationen sind möglich / *Legal combinations of devices:*

- TMS 3 (Art.-Nr. 4640) mit TOSCA-Workstation (Art.-Nr. 3107) und Software TOSCA (Art.-Nr. 3104)
TMS 3 (Model-No. 4640) with TOSCA Workstation (Model-No. 3107) and Software TOSCA (Model-No. 3104)

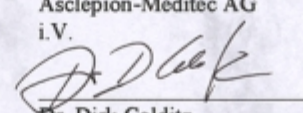
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This declaration is only valid with the declarations of conformity for each device. Changes of the single devices or combinations with other devices not mentioned without approval by Asclepion-Meditec AG will cause the loss of validity of this declaration.

Jena, 17.02.2000



Dr. Michael Dettelbacher
Vorstand / Director



Asclepion-Meditec AG
i.V.
Dr. Dirk Colditz
Qualitätsmanagement / Quality Management

660605032

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- Iomega ZIP is a registered trademark of Iomega Corporation.
- TMS-3 AutoTopographer is a registered trademark of Fortune Technologies.

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